



<NOTICE>

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<AGENCY TYPE='S'>DEPARTMENT OF AGRICULTURE

<SUBAGY>Animal and Plant Health Inspection Service

<DEPDOC>[Docket No. APHIS-2018-0042]

<SUBJECT>Availability of an Environmental Assessment for Field Testing of a Swine Influenza Vaccine, DNA

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice of availability.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared an environmental assessment concerning authorization to ship for the purpose of field testing, and then to field test, an unlicensed Swine Influenza Vaccine, DNA. Based on the environmental assessment, risk analysis, and other relevant data, we have reached a preliminary determination that field testing this veterinary vaccine will not have a significant impact on the quality of the human environment. We are making the documents available to the public for review and comment.

DATES: We will consider all comments that we receive on or before **November 9, 2018**.

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0042>.
- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2018-0042, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2018-0042> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

FOR FURTHER INFORMATION CONTACT: Dr. Donna Malloy, Operational Support Section, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 4700 River Road Unit 148, Riverdale, MD 20737-1231; phone (301) 851-3426, fax (301) 734-4314.

For information regarding the environmental assessment or the risk analysis, or to request a copy of the environmental assessment (as well as the risk analysis with confidential business information redacted), contact Dr. Patricia L. Foley, Risk Manager, Center for Veterinary Biologics, Policy, Evaluation, and Licensing, VS, APHIS, 1920 Dayton Avenue, P.O. Box 844, Ames, IA 50010; phone (515) 337-6100, fax (515) 337-6120.

SUPPLEMENTARY INFORMATION:

Under the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*), the Animal and Plant Health Inspection Service (APHIS) is authorized to promulgate regulations designed to ensure that veterinary biological products are pure, safe, potent, and efficacious before a veterinary biological product license may be issued. Veterinary biological products include viruses, serums, toxins, and analogous products of natural or synthetic origin, such as vaccines, antitoxins, or the immunizing components of microorganisms intended for the diagnosis, treatment, or prevention of diseases in domestic animals.

APHIS issues licenses to qualified establishments that produce veterinary biological products and issues permits to importers of such products. APHIS also enforces requirements concerning production, packaging, labeling, and shipping of these products and sets standards for the testing of these products. Regulations concerning veterinary biological products are contained in 9 CFR parts 101 to 124.

A field test is generally necessary to satisfy preclicensing requirements for veterinary biological products. Prior to conducting a field test on an unlicensed product, an applicant must obtain approval from the Animal and Plant Health Inspection Service (APHIS), as well as obtain APHIS' authorization to ship the product for field testing.

To determine whether to authorize shipment and grant approval for the field testing of the unlicensed product referenced in this notice, APHIS considers the potential effects of this product on the safety of animals, public health, and the environment. Based upon a risk analysis and other relevant data, APHIS has prepared an environmental assessment (EA) concerning the field testing of the following unlicensed veterinary biological product:

Requester: Antelope Valley Bios, Inc.

Product: Swine Influenza Vaccine, DNA.

Possible Field Test Locations: Minnesota, North Carolina, and Oklahoma.

The above-mentioned product is a DNA vaccine containing a hemagglutinin gene from swine influenza virus, subtype H3. The vaccine is intended for use in healthy swine 3 weeks of age or older, administered by intramuscular inoculation, as an aid in the prevention of disease due to swine influenza virus, subtype H3.

The EA has been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 *et seq.*), (2) regulations of the Council on

Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508), (3) USDA regulations implementing NEPA (7 CFR part 1b), and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

We are publishing this notice to inform the public that we will accept written comments regarding the EA from interested or affected persons for a period of 30 days from the date of this notice. Unless substantial issues with adverse environmental impacts are raised in response to this notice, APHIS intends to issue a finding of no significant impact (FONSI) based on the EA and authorize shipment of the above product for the initiation of field tests following the close of the comment period for this notice.

Because the issues raised by field testing and by issuance of a license are identical, APHIS has concluded that the EA that is generated for field testing would also be applicable to the proposed licensing action. Provided that the field test data support the conclusions of the original EA and the issuance of a FONSI, APHIS does not intend to issue a separate EA and FONSI to support the issuance of the associated product license, and would determine that an environmental impact statement need not be prepared. APHIS intends to issue a veterinary biological product license for this vaccine following satisfactory completion of the field test

provided no adverse impacts on the human environment are identified and provided the product meets all other requirements for licensing.

Authority: 21 U.S.C. 151-159.

<SIG><DATED>Done in Washington, DC, this 3rd day of October 2018.

<NAME>**Kevin Shea,**

<TITLE>*Administrator,*

Animal and Plant Health Inspection Service. </SIG>

<FRDOC> [FR Doc. 2018–21926 Filed 10–9–18; 8:45 am]

<BILCOD> BILLING CODE 3410–34–P

[FR Doc. 2018-21926 Filed: 10/9/2018 8:45 am; Publication Date: 10/10/2018]